COPY

Andrew J. Kahn, CA Bar #129776
ajk@dcbsf.com
Sarah Grossman-Swenson, CA Bar #259792
sgs@dcbsf.com
DAVIS COWELL & BOWE
595 Market St. #1400
San Francisco CA 94105
Telephone (415) 597-7200
Fax: (415) 597-7201
Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

UNITE HERE,

Plaintiff,

v.

FOOD & DRUG ADMINISTRATION,

Defendant.

CASE NO. SACV13-0227 JVS (MLGx)

COMPLAINT FOR INJUNCTIVE RELIEF UNDER FOIA
[5 USC § 552]

Plaintiff alleges:

JURISDICTION

1. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552(a)(4)(B). This court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331.

///

NATURE OF ACTION

2. This is an action under FOIA challenging Defendant FDA's unexplained insistence on redacting almost every portion of an inspector's report which identified actual or potential problems with a medical device implanted inside thousands of patients. FDA failed to explain its redactions beyond simply citing FOIA Exemption 4 (trade secrets or confidential commercial information, 5 USC §552(b)(4)), but such exemption cannot reasonably be construed to preclude release of information likely available from other sources such as the company's own published product descriptions, and not of aid to competitors in copying a company's product but instead likely showing the company put public health at risk. Construing the exemption to insulate from release all mention of patient ailments related to a medical devices would be contrary to the purpose of FOIA. Embarrassment due to exposure of public health risks is not an interest protected by Exemption 4. Plaintiff appealed administratively but this appeal has gone unaddressed for substantially longer than the statutory deadline for rendering of a decision.

VENUE

3. Venue lies in this district under 5 U.S.C. § 552(a)(4)(B) as the requested records are situated at the FDA office in Irvine, California within this district.

FACTS

4. Plaintiff UNITE HERE is a non-profit international labor organization which co-sponsors employee health benefit plans providing care to hundreds of thousands of UNITE HERE members and their beneficiaries, including implantable cardioverter defibrillator devices ("ICDs") and other products regulated by FDA.

5. Defendant FDA is a Department of the Executive Branch of the United States Government and constitutes an agency within the meaning of 5 U.S.C. § 552(f).

6. St Jude Medical Inc. ("SJM") is a for-profit publicly-held corporation based in Minnesota which manufactures and sells ICDs. It has maintained offices in Sylmar

California in which are located information concerning the testing, performance and evaluation of its Durata-brand ICDs .

7. SJM's ICDs are devices installed inside patients' chests to treat irregular heartbeats known as arrhythmias. They contain a cable (known as a "lead") which runs through the patients' veins into their hearts through which an electric shock is supposed to be provided by a battery-powered device installed inside the patient's chest.

8. FDA issued a recall of SJM's Riata-brand ICDs in a Class 1 recall, one of FDA's most serious classes, due to serious problems with its leads. The Wall Street Journal has reported claims by physicians that years before SJM and FDA took action as to these devices, several physicians had warned SJM of problems with the devices.

9. SJM's later brand of ICD known as the Durata has also been questioned publicly in the press by some prominent physicians. The Durata has been implanted in thousands of patients. SJM has posted publicly hundreds of pages of information about the materials used inside the Durata and their configuration, and about the problems SJM has sought to avoid.

10. In October 2012, FDA inspectors reviewed SJM-Sylmar's procedures and records for testing its Durata ICDs and issued a written inspectional observations report on FDA form number 483, pursuant to FDA's authority under 21 USC §374. Such reports are commonly known in the industry as "483 Reports". The 483 Report on SJM-Sylmar was publicly-posted in redacted form by SJM as part of an SEC filing. On October 31, 2012, Plaintiff requested from FDA an unredacted version of such report, explaining why Plaintiff believed the redactions in SJM's posting were excessive under the law. A true and correct copy of Plaintiff's request is attached hereto as Exhibit A and incorporated herein.

11. On November 21, 2012, FDA responded to Plaintiff's request by notifying Plaintiff that it had posted on the FDA website a somewhat-less-redacted version of the 483 Report, a true and correct copy of which is attached hereto as Exhibit B.

12. However, the only redactions eliminated by FDA were those identifying the product involved as Durata, but the fact of its manufacture at this facility and its review by FDA inspectors had already been revealed by SJM in its own posting and elsewhere. FDA has still redacted every description of the problems considered by the inspector and SJM so that it is impossible to know whether they were purely cosmetic or instead serious risks of device failure and heart attack. For example, here is how several inspectional findings look after the redactions:

"You failed to follow your written test procedures during design verification testing of your [ ] test which ensures the [ ] is not greater than [ ] to prevent a potential [ ]." (Para. 2B).

"Your Durata risk analyses (2007) identified canine testing as a mitigation addressing [ ]. *** you failed to evaluate one of the study results which stated, [ ]." . (Para. 3A).

"Your [ ] out for all [ ] leads states a severity of [ ] and probability of [ ] when your design team stated the Durata design decreased the risk of this [ ] root cause." (Para. 3B).

13. On November 26, 2012, Plaintiff offered FDA further written explanation of why Plaintiff believed the redactions contrary to law. A true and correct copy of such letter without its exhibits is attached hereto as Exhibit C and incorporated herein.

14. On December 5, 2012, FDA denied Plaintiff's request. A true and correct copy of this denial letter is attached hereto as Exhibit D.

15. On December 14, 2012, Plaintiff filed a timely administrative appeal. A true and correct copy of this appeal without its exhibits is attached hereto as Exhibit E and incorporated herein.

16. Under FOIA, 5 USC §552(a)(6), such an appeal is supposed to be resolved within 20 working days, or 30 working days if unusual circumstances are invoked by the agency, and a requester is deemed to have exhausted its administrative remedies if the agency does not comply with such deadline.

17. To date FDA has not responded to the appeal other than to acknowledge receipt in mid-December. Accordingly, Plaintiff has exhausted its administrative remedies.

18. At no point in the administrative process have FDA staff explained their reasons for redacting the report beyond checking boxes on a form citing Exemption 4 and related regulations in Exhibit D hereto.

FIRST CAUSE OF ACTION:

VIOLATION OF FOIA, 5 USC §552

19. Plaintiff incorporates herein the foregoing allegations.

20. FDA has wrongfully withheld the requested record. For a variety of reasons FDA cannot carry its burden of showing the requested information is covered by Exemption 4, including:

(a) FDA deleted all discussion of problems with the devices and patients so as to make it impossible to know whether FDA and SJM were merely concerned with cosmetic issues or instead with serious health issues, but the issues arising with ICD devices and patients and the specific components and configuration of Durata are already a matter of public record and not even close to a trade secret, for indeed SJM discusses them at length on its website;

(b) information which may embarrass FDA and SJM by showing there has been lax safety review up until now is not within the protection of Exemption 4, which instead protects only information useful in ordinary competition such as revealing a formula which a competitor could borrow from SJM. UNITE HERE is not a competitor and there is no evidence that competitors would use the information in competition which is being sought by UNITE HERE. Nor is there any evidence that FDA's future access to information would be retarded by release of the information sought by Plaintiff, as FDA has ample power both under the law and in practice to obtain information from medical device manufacturers.

WHEREFORE, Plaintiff prays:

1. For an order expediting these proceedings;

2. For an order directing FDA to either produce to Plaintiff an unredacted copy of the 483 Report on SJM's Durata testing and review, or at a minimum to produce such copy to the Court *en camera* for the Court's review for release to Plaintiff;

3. For an award of attorneys fees pursuant to §552(a)(4)(E);

4. For Plaintiff's costs of suit herein;

5. For issuance of a written finding pursuant to §552(a)(4)(F) that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily and capriciously with respect to the withholding; and

6. For such other and further relief as the Court deems just and proper.

DATED: Feb. 8, 2013 DAVIS, COWELL & BOWE, LLP

By: _____
Andrew J. Kahn, CA Bar #129776
Sarah-Grossman Swenson, CA Bar #259792

Attorneys for Plaintiff

EXHIBIT A

DAVIS, COWELL & BOWE, LLP

Counselors and Attorneys at Law

October 31, 2012

San Francisco

McCracken, Stemerman & Holsberry

By Email

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
12420 Parklawn Drive
ELEM-1029
Rockville, MD 20857

Commander Sean Creighton
Alonza Cruse, District Director
FDA District Office
19701 Fairchild
Irvine CA 92612-2506

RE: *Request for Unredacted 483 Report on St Jude Medical Inc. facility in Sylmar CA*

Dear FDA officials:

On behalf of nonprofit UNITE HERE, we request pursuant to FOIA a copy of the unredacted version of the 483 Report issued earlier this month by the FDA to St Jude Medical regarding its Sylmar California facility. A redacted copy of this report is attached (this was posted publicly by St Jude to the SEC website on October 24, 2012).

The redactions sought by the Company exceed those permitted by FOIA's Exemption 4. Indeed, the redactions go so far as to prevent the reader from determining whether this facility manufactures medical devices at all. (However, confidentiality as to what is being manufactured has been waived by this Company by revealing in the SEC 8K filing accompanying this posting that this facility "manufacture[s] cardiac rhythm management devices.").

Most of the redactions appear designed to prevent customers from learning about likely safety problems, rather than preventing release of trade secrets or similar proprietary information about these devices. This is contrary to the caselaw interpreting Exemption 4:

> "[t]he important point for competitive harm in the FOIA context ... is that it be limited to harm flowing from the affirmative use of proprietary information by competitors. Competitive harm should not be taken to mean simply any injury to competitive position, as might flow from customer or employee disgruntlement or from the embarrassing publicity attendant upon public revelations concerning, for example, illegal or unethical payments to

government officials or violations of civil rights, environmental or safety laws."

Public Citizen Health Research Group v. FDA, 704 F. 2d 1280, 1291 n. 30 (D.C. Cir. 1983). Accord, *CNA Fin'l v. Donovan*, 830 F.3d 1132 (D.C. Cir. 1987).

Concern about the safety of St Jude's cardiac devices is far from speculative, given the recent Class 1 recall of its Riata cardiac devices and a recent Wall Street Journal article reporting on several physicians having reported problems with these devices to this Company years before the Company issued any warning. Thus release of the redacted data is very much in the public interest. UNITE HERE is not affiliated with any competitor of this Company but rather is a hotel workers industry union dealing daily with the crushing costs of healthcare in the U.S. –costs augmented by large-scale failures of expensive medical devices.

We request expedited treatment of this request because the problems identified by FDA Staff in the Report may well be impacting devices already being distributed to patients by this Company. The fact that some information in this report was immediately posted by this Company confirms that prompt receipt of information by the public about the matters covered by this report is very much in the public interest. Thank you for your consideration.

Respectfully,

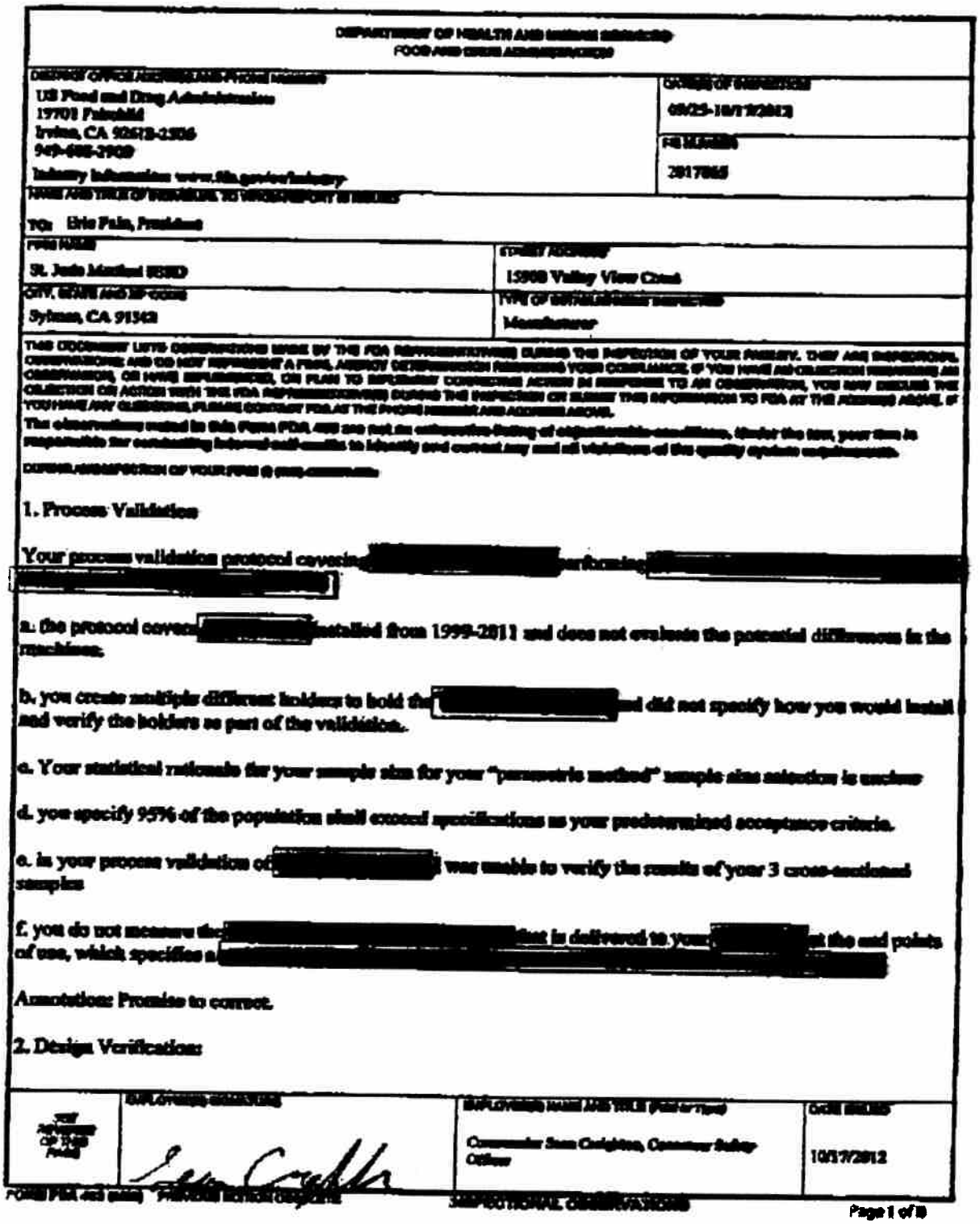
Andrew Kahn

Andrew Kahn
Attorney for UNITE HERE

AJK:ja

EX-99.1 2 stjude124442_ex99-1.htm FDA FORM 483

Exhibit 99.1



DEPARTMENT OF HEALTH AND [redacted]
FOOD AND DRUG ADMINISTRATION

US Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506
949-608-2900
Industry Information: www.fda.gov/ora/industry

DATE(S) OF INSPECTION
09/25-10/17/2012

FEI NUMBER
2017865

TO: Eric Fain, President

FIRM NAME
St. Jude Medical SJMD

STREET ADDRESS
15900 Valley View Court

CITY, STATE AND ZIP CODE
Sylmar, CA 91342

TYPE OF ESTABLISHMENT INSPECTED
Manufacturer

THIS DOCUMENT LISTS CONDITIONS OBSERVED BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THIS OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

The observations noted on this Form FDA 483 are not an adjudicated finding of objectionable conditions. Under the law, your firm is responsible for conducting internal audits to identify and correct any and all violations of the quality system requirements.

DISCUSSION OF YOUR FDA 483 OBSERVATIONS

1. Process Validation

Your process validation protocol covering [redacted] performing [redacted]

a. the protocol covers [redacted] installed from 1999-2011 and does not evaluate the potential differences in the machines.

b. you create multiple different holders to hold the [redacted] and did not specify how you would install and verify the holders as part of the validation.

c. Your statistical rationale for your sample size for your "parametric method" sample size selection is unclear

d. you specify 95% of the population shall exceed specifications as your predetermined acceptance criteria.

e. in your process validation of [redacted] was unable to verify the results of your 3 cross-sectional samples

f. you do not measure the [redacted] that is delivered to your [redacted] at the end points of use, which specifies a [redacted]

Annotations: Promise to correct.

2. Design Verification:

SIGNATURE OF FDA REPRESENTATIVE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	[signature]	Commander Sam Creighton, Consumer Safety Officer	10/17/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE SUPERSEDES: [redacted]

Page 1 of 19

*Redacted by the Company based on its good faith interpretation of Freedom of Information Act (FOIA) exemption (b)(4).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/ForIndustry	09/25-10/17/2012
	FEI NUMBER 2017965

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical SJMD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

A. Your design verification activities were inadequate in that you failed to validate 3 test methods you created in-house to verify your design inputs during your design verification, for example:

a. [redacted] input specified for verification testing: [redacted] of the [redacted] shall be [redacted] Non-validated test method: [redacted]

b. [redacted] design input specified for verification testing: [redacted] shall not change by more than [redacted] Non-validated test method: [redacted]

b(1). You are currently conducting design verification testing using the [redacted] method testing [redacted] model number: [redacted] [redacted] model [redacted] and model [redacted]

c. [redacted] design input specified for verification testing: (2 items tested) in [redacted] condition shall be maximum [redacted] and in [redacted] condition minimum of [redacted] Non-validated test method: [redacted]

B. You failed to follow your written test procedure during design verification testing of your [redacted] which ensures the [redacted] is not greater than [redacted] to prevent a potential [redacted] Your procedures require each [redacted] to be tested 5 times and the mean of the 5 tests is considered your test result. During your design verification you only tested each [redacted] one time to determine your design verification results as opposed to determining the mean of 5 tests results per [redacted]

C. You conducted your [redacted] verification to verify the [redacted] is not excessive per product specification requirements" on 05/07/07 which was prior to your approval of your [redacted] inputs revision #004, Document number 60910874 which occurred on 07/16/07.

SIGNATURE OF THIS PERSON	EMPLOYEE'S SIGNATURE	EMPLOYEE'S NAME AND TITLE (Please Type)	DATE ISSUED
		Commander Sara Creighton, Consumer Safety Officer	10/17/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 2 of 3

*Redacted by the Company based on its good faith interpretation of Freedom of Information Act (FOIA) exemption (b)(4).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/12/2012 2017865
TO: Eric Palm, President	
St. Jude Medical SJDC	15900 Valley View Court
Sylmar, CA 91342	Manufacturer

D. Your [redacted] design verification activity to verify the design input of "the [redacted] shall be [redacted]" was conducted on 06/07/07 which was after you implemented [redacted] into commerce as part of your design validation.

Annotation: Promises to correct.

3. Design Validation:

A. Your [redacted] risk analyses (2007) identified canine testing as a mitigation addressing [redacted]. In the mitigation you reference study OVS00003 as your design verification and it was inadequate in that:

a. It did not include predetermined acceptance criteria corresponding to [redacted]
b. A review of your approval of the verification found 4 of the total population of 30 canines implanted to support a samples size of 21 canines tested but [redacted]
c. you failed to evaluate one of the study results which stated [redacted].

B. Your [redacted] is inadequate in that it combines different [redacted] devices, for example:

a. You [redacted] assigned a severity of [redacted] and a probability of [redacted] when your design team stated the [redacted]

b. You [redacted] assigned a severity of [redacted] and a probability of [redacted] when your design team stated the [redacted]

Annotation: Promise to correct.

SIGNATURE OF THE HEAD OF THE AGENCY	EMPLOYEE SIGNATURE	EMPLOYEE NAME AND TITLE (Print or Type)	DATE ISSUED
		Consumer Safety Officer	10/17/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 5 of 6

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012 2017865

TO: Eric Pain, President

St. Jude Medical SJM	15900 Valley View Court
Sylmar, CA 91342	Manufacturer

4. Design Changes

[redacted] Design Changes

You documented [redacted] your [redacted] predetermined acceptance criteria of [redacted] during your design verification testing. You then changed your [redacted] in the [redacted] from [redacted], produced and tested 24 newly manufactured [redacted] and approved your design verification without determining the validity of any of your other design verification activities that were conducted using the [redacted] manufactured under previously approved specifications (design inputs).

Annotation: Promise to correct.

5. Design History File:

Your firm was unable to clearly identify the full content of your [redacted] design history file, for example: I was unable to determine when your firm approved your [redacted] design inputs, outputs, verification, validation, design transfer and when you conducted your final approval of your [redacted] design. I was also unable to determine which inputs were changed or unchanged from 1997 onward which is the origination of your [redacted] design.

Annotation: Promise to correct.

6. Training:

A. Internal Auditor Training:

Your training of your internal auditors is inadequate in that your audit team audited the [redacted] design project in January of 2012 when after 6 days of inspectional requests of your firm to provide the [redacted] design history file I was unable to determine when your firm approved your [redacted] design inputs, outputs, verification, validation,

SIGNATURE OF THE PERSON	EMPLOYEE'S SIGNATURE	EMPLOYEE'S NAME AND TITLE (Please Type)	DATE ISSUED
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012 2017865

TO: Eric Fain, President

St. Jude Medical IRBD	15900 Valley View Court
Sylmar, CA 91342	Manufacturer

design transfer and when you conducted your final approval of your [redacted] design. I was also unable to determine which inputs were changed or unchanged from 1997 onward which is the origination of your [redacted] design.

B. Design Training:
You have inadequate training of design controls, for example:
a. After 6 days of inspectional requests I was unable to determine which design inputs were changed or unchanged from 1997 to present day.
b. 4 personnel approved your design validation study with an ambiguous input

Annotation: Promise to correct.

7. CAPA system:

A. Your CAPA system is inadequate in that in reviewing 11 of your recently closed CAPAs I found:

a. two were closed and did not state a verification of the effectiveness would be performed.

b. two were closed and stated "no effectiveness check is required" with no justification, which is required by your procedures if no verification check is performed.

c. six of the CAPAs are closed and state an effectiveness check is going to be done in 6-9 months. None of the 11 CAPAs reviewed, including these 6, specify how you are going to verify your effectiveness.

d. PIR10-007 was closed on 03/25/2011 and an employee documented that the CAPA was not effective on 10/20/2011 and the problem o[redacted]reoccurred, implemented two actions to correct the original problem and requested a new effectiveness check be performed at a later date. This CAPA was not re-opened nor was there a separate CAPA opened after the original CAPA action taken was determined to be ineffective. There is no document control dictating which documents are part of or not part of this CAPA.

e. You failed to re-evaluate and update your risk analysis for CAPA PIR 10-007 when the mitigation identified in

SIGNATURE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Please Print)	DATE ISSUED
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 5 of 8

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/ice/industry	09/25-10/17/2012
	FEI NUMBER 2017869

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical SJRD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

the risk analysis failed and you continued to have the problem of [redacted] and then implemented further actions to solve the problem

B. Your Corrective Action #PIR-10-085 for your [redacted] was inadequate in that you failed to evaluate the validity of some of your [redacted] design verification and validation activities.

Annotation: Promise to correct.

8. CAPA Procedures:
Your CAPA procedures are inadequate in that they do not address:

1. Determining whether the action taken adversely affects the finished device,

2. Identify data sources you are going to analyze, such as complaints and MDRs.

3. verifying or validating the effectiveness of a CAPA

And the procedures state you will determine the effectiveness of the CAPA after the CAPA is closed

Annotation: Promise to correct.

9. Complaint Files:

Your complaint handling procedures are inadequate in that:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Sue Crum	Commander Sean Creighton, Consumer Safety Officer	10/17/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 6 of 8

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/ora/industry	09/25-10/17/2012 2017969

TO: Eric Fain, President

St. Jude Medical IEMD	15900 Valley View Court
Sylmar, CA 91342	Manufacturer

a. Your procedures do not dictate that you will make a decision as to whether an investigation is necessary.

b. A review of your [redacted] complaint file(s)
1. you did not specify whether an investigation was necessary
2. Your decision of whether this complaint was a medical device reportable event was conflicting in that you stated [redacted] as a justification for the non-reportable event when the [redacted]

Annotation: Promise to correct.

10. Document Control:
Your document control is inadequate in that while reviewing:
a. CAPA/PIR 10-005 I was unable to determine which document were included in the CAPA and which were not, for example the attachment pages are not identified as being associated with the CAPA and a separate [redacted] was not identified as being part of your CAPA.

b. [redacted] complaint I was unable to determine which documents were included in the complaint as the documents are not identified as being linked to the complaint and there is no individual complaint identifier.

Annotation: Promise to correct.

11. Control of Inspection, Measuring, and Test Equipment

Your [redacted] procedure and implementation is inadequate in that your procedures dictate [redacted] and you are performing verification, unless it falls out of your [redacted] equipment; for example:

SIGNATURE OF THE PERSON	EMPLOYEE SIGNATURE	EMPLOYEE'S NAME AND TITLE (Please Type)	DATE
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 3 of 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

US Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506
949-608-2900
Industry Information: www.fda.gov/ora/industry

DATE(S) OF INSPECTION
09/25-10/17/2012

FEI NUMBER
3017868

TO: Eric Fain, President

FIRM NAME
St. Jude Medical

STREET ADDRESS
15900 Valley View Court

CITY, STATE AND ZIP CODE
Sylmar, CA 91342

TYPE OF ESTABLISHMENT INSPECTED
Manufacturer

a. You failed to follow your procedures which require you to [redacted]

Annotations: Promise to correct.

STK

	EMPLOYEE'S SIGNATURE	EMPLOYEE'S NAME AND TITLE (Print or Type)	DATE ISSUED
THIS ACKNOWLEDGES ONLY RECEIPT OF THIS AUDIT		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 8 of 8

EXHIBIT B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	FEI NUMBER
TO: Eric Fain, President	2017865
FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

The observations noted in this Form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Process Validation

Your process validation protocol covering (b)(4) different machines performing (b) (4) of (b) (4) and (b) (4) was inadequate in that:

a. the protocol covers (b)(4) machines installed from 1999-2011 and does not evaluate the potential differences in the machines.

b. you create multiple different holders to hold the leads during (b) (4) and did not specify how you would install and verify the holders as part of the validation.

c. Your statistical rationale for your sample size for your "parametric method" sample size selection is unclear

d. you specify 95% of the population shall exceed specifications as your predetermined acceptance criteria.

e. in your process validation of (b) (4) was unable to verify the results of your 3 cross-sectioned samples

f. you do not measure the pressure and flow of the (b) (4) that is delivered to your (b) (4) at the end points of use, which specifies a maximum of (b) (4) and a (b) (4) per (b) (4) recommended consumption flow

Annotation: Promise to correct.

2. Design Verification:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012
	FEI NUMBER 2017865

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

A. Your design verification activities were inadequate in that you failed to validate 3 test methods you created in-house to verify your design inputs during your design verification, for example:

a. Durata input specified for verification testing: (b) (4) of the (b) (4) ip shall be (b) (4) per (b) (4) Non-validated test method: (b) (4)

b. Durata design input specified for verification testing: (b) (4) shall not change by more than (b) (4) %. Non-validated test method (b) (4) test.

b(i). You are currently conducting design verification testing using th (b) (4) test method testing (b) (4) leads (model number (b) (4) and IDE (b) (4) (b) (4) model (b) (4) and model (b) (4).

c. Durata design input specified for verification testing: (2 items tested) ir (b) (4) condition shall be maximum (b) (4) (b) (4) and (b) (4) condition minimum of (b) (4) (b) (4) Non-validated test method: (b) (4)

B. You failed to follow your written test procedure during design verification testing of your (b) (4) test, which ensures th (b) (4) s not greater than (b) (4) (b) (4) to prevent a potential (b) (4) Your procedures require each lead to be tested 5 times and the mean of the 5 tests is considered your test result. During your design verification you only tested each lead one time to determine your design verification results as apposed to determining the mean of 5 tests results per lead.

C. You conducted your Durata (b) (4) esign verification to verify the (b) (4) ' on 06/07/07 which was prior to your approval of your Durata lead inputs revision #004, Document number 60010874 which occurred on 07/16/07.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012
	FEI NUMBER 2017865

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

D. Your (b) (4) design verification activity to verify the design input of (b) (4) (b) (4) was conducted on 06/07/07 which was after you implanted (b) leads into canines as part of your design validation.

Annotation: Promise to correct.

3. Design Validation:

A. Your Durata risk analyses (2007) identified canine testing as a mitigation addressing (b) (4) (b) (4) In the mitigation you reference study (b) (4) as your design verification and it was inadequate in that:

a. It did not include predetermined acceptance criteria corresponding to (b) (4)

b. A review of your approval of the verification found 4 of the total population of 30 canines implanted to support a samples size of 21 canines tested had (b) (4) (b) (4)

c. you failed to evaluate one of the study results which stated (b) (4) (b) (4)

B. Your Durata design risk analysis (b) (4) is inadequate in that it combines different recalled and not recalled devices, for example:

a. Your "(b) (4) out for all (b) (4) leads states a severity of (b) (4) and a (b) when your design team stated the Durata design decreased the risk of this (b) (4) root cause.

b. Your "(b) (4)" for all (b) (4) leads states a severity of (b) (4) and a probability of (b) (4) when your design team stated the Durata design decreased the risk of this (b) (4) root cause.

Annotation: Promise to correct.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012
	FEI NUMBER 2017865

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

4. Design Change:

(b) (4) Design Change:
You documented (b) (4) of (b) (4) devices failed your "(b) (4) test" predetermined acceptance criteria of "(b) (4) %" during your design verification testing. You then changed your (b) (4) in the (b) (4) from (b) (4) to (b) (4) inches, produced and tested (b) (4) newly manufactured (b) (4) leads and approved your design verification without determining the validity of any of your other design verification activities that were conducted using the (b) (4) leads manufactured under previously approved specifications (design inputs).

Annotation: Promise to correct.

5. Design History File:
Your firm was unable to clearly identify the full content of your Durata design history file, for example: I was unable to determine when your firm approved your Durata design inputs, outputs, verification, validation, design transfer and when you conducted your final approval of your Durata design. I was also unable to determine which inputs were changed or unchanged from 1997 onward which is the origination of your Durata design.

Annotation: Promise to correct.

6. Training:

A. Internal Auditor Training:
Your training of your internal auditors is inadequate in that your audit team audited the Durata design project in January of 2012 when after 6 days of inspectional requests of your firm to provide the Durata design history file I was unable to determine when your firm approved your Durata design inputs, outputs, verification, validation,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900	09/25-10/17/2012
Industry Information: www.fda.gov/oc/industry	FEI NUMBER 2017865

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

design transfer and when you conducted your final approval of your Durata design. I was also unable to determine which inputs were changed or unchanged from 1997 onward which is the origination of your Durata design.

B. Design Training:
You have inadequate training of design controls, for example:
a. After 6 days of inspectional requests I was unable to determine which design inputs were changed or unchanged from 1997 to present day.
b. 4 personnel approved your design validation study with an ambiguous input

Annotation: Promise to correct.

7. CAPA system:

A. Your CAPA system is inadequate in that in reviewing 11 of your recently closed CAPAs I found:

a. two were closed and did not state a verification of the effectiveness would be performed.

b. two were closed and stated "no effectiveness check is required" with no justification, which is required by your procedures if no verification check is performed.

c. six of the CAPAs are closed and state an effectiveness check is going to be done in 6-9 months. None of the 11 CAPAs reviewed, including these 6, specify how you are going to verify your effectiveness.

d. PIR10-007 was closed on 03/25/2011 and an employee documented that the CAPA was not effective on 10/20/2011 and the problem of (b) (4) in your lead continued, implemented two actions to correct the original problem and requested a new effectiveness check be performed at a later date. This CAPA was not re-opened nor was there a separate CAPA opened after the original CAPA action taken was determined to be ineffective. There is no document control dictating which documents are part of or not part of this CAPA.

e. You failed to re-evaluate and update your risk analysis for CAPA PIR 10-007 when the mitigation identified in

EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Commander Sean Creighton, Consumer Safety Officer	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012
	FEI NUMBER 2017865

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

the risk analysis failed and you continued to have the problem of (b) (4) (b) (4) nd then implemented further actions to solve the problem

B. Your Corrective Action #PIR-10-005 for your Riata lead was inadequate in that you failed to evaluate the validity of some of your Durata lead design verification and validation activities.

Annotation: Promise to correct.

8. CAPA Procedures:
Your CAPA procedures are inadequate in that they do not address:

1. Determining whether the action taken adversely affects the finished device,

2. Identify data sources you are going to analyze; such as complaints and MDRs.

3. verifying or validating the effectiveness of a CAPA

And the procedures state you will determine the effectiveness of the CAPA after the CAPA is closed

Annotation: Promise to correct.

9. Complaint Files:

Your complaint handling procedures are inadequate in that:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Sean Creighton	Commander Sean Creighton, Consumer Safety Officer	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012
	FEI NUMBER 2017865

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

a. Your procedures do not dictate that you will make a decision as to whether an investigation is necessary.

b. A review of your Durata Model 7121 SN AHD32782 complaint found:
1. you did not specify whether an investigation was necessary
2. Your decision of whether this complaint was a medical device reportable event was conflicting in that you stated "not implanted" as a justification for the non-reportable event when the lead was implanted and then removed during the implant procedure.

Annotation: Promise to correct.

10. Document Control:
Your document control is inadequate in that while reviewing:
a. CAPA#PIR 10-005 I was unable to determine which document were included in the CAPA and which were not, for example the attachment pages are not identified as being associated with the CAPA and a separate "knowledge transfer to future HV lead designs" memorandum was not identified as being part of your CAPA.

b. Durata Model 7121 SN AHD32782 complaint I was unable to determine which documents were included in the complaint as the documents are not identified as being linked to the complaint and there is no individual complaint identifier.

Annotation: Promise to correct.

11. Control of Inspection, Measuring, and Test Equipment

Your calibration procedure and implementation is inadequate in that your procedures dictate calibration and you are performing verification, unless it falls out of your tolerances upon which you calibrate the equipment; for example:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	FEI NUMBER
TO: Eric Fain, President	2017865
FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	Manufacturer

a. You failed to follow your procedures which require you to calibrate th(b) (4) in (b) (4) of your (b) (4) used to (b) (4) leads. In actuality you (b) (4)

Annotation: Promise to correct.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Commander Sean Creighton, Consumer Safety Officer	10/17/2012

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

EXHIBIT C

DAVIS, COWELL & BOWE, LLP

Counselors and Attorneys at Law

San Francisco

595 Market Street, Suite 1400
San Francisco, California 94105
415.597.7200
fax 415.597.7201

Jerry S. Jenson (CA)
Steven L. Stemerman (CA, NV)
Richard G. McCracken (CA, NV)
W. David Holsberry (CA, NV)
Elizabeth Ann Lawrence (CA, NV, AZ)
Andrew J. Kahn (CA, NV, AZ)
John J. Davis, Jr. (CA)
Clarence E. Culp (CA, NV)
Kristin L. Martin (CA, NV, HI)
Eric B. Myers (CA, NV)
Paul L. More (CA, NV, MA)
Juan Varela (CA, AZ)
Sarah Grossman-Swenson (CA, NV)
Elizabeth O. Hinckle (CA)
Neal Miller (CA)
Kirsten Skogstad (CA)
Elizabeth H. Jackson (CA)

Robert P. Cowell (1931-1980)

Of Counsel:
Philip Paul Bowe (CA)

McCracken, Stemerman & Holsberry

1630 S. Commerce Street, Suite A-1
Las Vegas, Nevada 89102
702.386.5107
Fax 702.386.9848

November 26, 2012

By Email (Sarah.Kotler@fda.hhs.gov) and 2-day mail

Sarah Kotler
Denials & Appeals Officer
Division of Freedom of Information
U.S. Food & Drug Administration
12420 Parklawn Drive, Room 1018
Rockville, MD 20857

RE: UNITE HERE's FOIA Request for 483 report on St Jude Medical – Sylmar (10/12), FDA FOIA No. 2012-8094

Dear Ms. Kotler:

Thank you to FDA Staff for your preliminary response to our FOIA request of 10/31/12 for this report. However, we believe the preliminary redactions exceed those permitted by Exemption 4. Two established principles of Exemption 4 caselaw are that (1) information which is embarrassing to a company because it may suggest a safety problem is not confidential under Exemption 4; and (2) information in a government record which is available to the public in another form is also not confidential under Exemption 4. We believe both principles were not fully applied here.

As to Issue #1, Staff redacted several pieces of information which are not secret formula unique to St Jude Medical ("SJM") but rather actual or potential problems with its devices (or with many ICD devices). The public is entitled to know which problems are being examined by this ICD manufacturer (and reviewed by FDA), and which problems are being ignored. For example, on page 2 para B there is a reference to a test which is supposed to avoid a problem (apparently a problem for physicians and patients), but the problem has been deleted: "test, which ensure the [ ] is not greater than [ ] to prevent a potential [ ]." (In addition to knowing what problems are being considered, the public is also entitled to know what tolerances are being used).

It is not as if the risks to ICD devices are themselves a trade secret: the failures of SJM's prior model (the Riata) in resisting abrasion resulting in conductors extruding and/or electrical abnormalities have become very public. SJM's own advertising claims Durata is superior in avoiding these failures to earlier Riata models and to its competitors. Ex. 1 hereto. Further risks are presented on SJM's website. Ex. 2. Access to the redacted data will allow physicians and patients to assess the accuracy of such advertising about problem avoidance.

Similarly-inappropriate redactions of information about problems occurred in the following instances:

p. 3 para. 3(A)("a mitigation addressing [ ]")

p. 3 para. 3(A(b)("4 of the total population of 30 canines implanted to support a samples size of 21 had [ ]")

p. 3 para. 3(A)(c)("you failed to evaluate one of the study results which stated [ ]")

p. 3 para. 3 (B) two references to "severity of [ ] and a probability of [ ] when your design team stated the Durata design decreased the risk of this [ ] root cause."

p. 5 para. 7 (A)(d)("the problem of [ ] in your lead continued")

pp. 5-6 para. 7(A)(e)("the mitigation identified in the risk analysis failed and you continued to have the problem of [ ]")

As to Issue #2, the attached exhibits contain data released by SJM on its website or through the media. We suspect some redactions may be of the name of the Optim insulating material used in Durata and/or components of Optim. This is not confidential as SJM boasts about using Optim and describes what its components are. Some redactions may be of the configuration of wires and insulation inside the Durata lead, but again these have already been made public (and touted) by SJM. Further, SJM boasts about various supportive studies and one of these may be the study about which information was redacted on p. 3 para. 3A.

Neither the public interest, nor the Company's own interest in being forthright with its current and potential customers, are served by these redactions. We therefore thank you for reconsidering the preliminary redactions from this 483 report.

Respectfully,

Andrew Kahn
Attorney for UNITE HERE

AJK:ja
Attachments

INDEX OF EXHIBITS

Exhibit No.	Description
1	St. Jude Medical, "Fluent in Fact" Durata Lead Reliability
2	St. Jude Medical, Durata Indications, Contraindications, Warnings, Precautions & Potential Adverse Events
3	St. Jude Medical, ICD Lead Design and Long-Term Performance
4	St. Jude Medical, Durata Product Performance
5	St. Jude Medical, Durata Comparison
6	St. Jude Medical, Durata Defibrillation Lead
7	St. Jude Durata, Defibrillation Lead Product Highlights
8	New York Times, "New Misgivings about St. Jude Heart Device," 11/21/12
9	New York Times, "Cardiologist Issues Alert on St. Jude Heart Device," 8/21/12
10	St. Jude Medical, Miscellaneous Product Information

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Date: DEC 0 5 2012

Request Number: 2012-8094

Andrew Kahn
Davis Cowell & Bowe, LLP
595 Market St., Ste 1400
San Francisco, CA 94105

Subject of Request: St. Jude Medical

Dear Sir/Madam:

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA). I apologize for any delay in responding to you. The paragraphs checked below apply to your request:

[X] The 483 is posted to **www.fda.gov**. We are denying your request for an unredacted copy of the document.

[ ] We are denying your entire request.

[X] The following exemption(s) of FOIA, 5 U.S.C. 552, indicated by an "X" is/are the authority for denying you access to the non-disclosable material. We have enclosed copies of FOIA and regulations for your information.

[ ] (b)(1) National security information concerning the national defense or foreign policy
[ ] (b)(2) Internal rules and practices
[ ] (b)(3) Prohibited from disclosure by other laws
[X] (b)(4) Trade secret and confidential commercial information
[ ] (b)(5) Certain interagency and intra-agency communications
[ ] (b)(6) Information about individuals in personnel, medical and similar files when disclosure would constitute a clearly unwarranted invasion of privacy
[ ] (b)(7) Records or information compiled for law enforcement purposes when disclosure
  [ ] (A) could reasonably be expected to interfere with enforcement proceedings
  [ ] (B) would deprive a person of a right to a fair trial or an impartial adjudication
  [ ] (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy

[ ] (D) could reasonably be expected to disclose the identity of a confidential source
[ ] (E) would disclose techniques, procedures or guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law
[ ] (F) could reasonably be expected to endanger the life or physical safety of an individual

[X] The following section(s) of the implementing regulations of the Department of Health and Human Services (DHHS) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

[ ] 5.63
[ ] 5.64
[X] 5.65
[ ] 5.66
[ ] 5.67

[ ] 5.68(a)
[ ] 5.68(b)
[ ] 5.68(c)
[ ] 5.68(d)
[ ] 5.68(e)
[ ] 5.68(f)
[ ] Other:

[X] The following section(s) of the implementing regulations of FDA and reason(s) applicable to this denial is/are indicated by an :X". The regulations are contained in the Code of Federal Regulations (CFR), Title 21.

[X] 20.61(c) Trade secret and confidential commercial information.

[X] FDA's Regulations at CFR Part 20 are available at:
http:www.access.gpo.gov/nara/cfr/waisidx_04/21cfr20_04.html

[X] Other laws, in addition to FOIA, may prohibit disclosure of the information you requested. The following law(s) applicable to this denial is/are indicated by an "X".

[ ] 18 U.S.C. 1905 [Federal Trade Secrets Act]
[ ] 21 U.S.C. 331(j) [Federal Food, Drug, and Cosmetic Act]
[ ] 21 U.S.C. 360j(c) [Federal Food, Drug, and Cosmetic Act]
[ ] 5 U.S.C. 107(a)(2) Appendix 4 [Ethics in Government Act]

[X] The estimated volume of records we are denying is: Redactions to 483.

The Department of Health and Human Services' implementing regulations, 45 CFR 5.34, set forth the procedures for you to follow if you decide to appeal this decision not to provide you with the information you requested. Your appeal should be sent within 30 days from the date you receive this letter to the Director, News Division, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services. Should you choose to send your appeal through the U.S. Postal Service, please mail it to 7700 Wisconsin Avenue, Suite 920, Bethesda, MD 20857. Should you choose to send your appeal through a private courier service, please send it to 7700 Wisconsin Avenue, Suite 920, Bethesda, MD 20814. Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

Sincerely yours,

Frederick J. Sadler
Director
Division of Freedom of Information

EXHIBIT E

UNITE-2836

COWELL & BOWE, LLP

Counselors and Attorneys at Law

San Francisco

595 Market Street, Suite 1400
San Francisco, California 94105
415.597.7200
Fax 415.597.7201

Barry S. Jellison (CA)
Steven L. Stemerman (CA, NV)
Richard G. McCracken (CA, NV)
W. David Holsberry (CA, NV)
Elizabeth Ann Lawrence (CA, NV, AZ)
Andrew J. Kahn (CA, NV, AZ)
John J. Davis, Jr. (CA)
Florence E. Culp (CA, NV)
Kristin L. Martin (CA, NV, HI)
Eric B. Myers (CA, NV)
Paul L. More (CA, NV, MA)
Sarah Varela (CA, AZ)
Sarah Grossman-Swenson (CA, NV)
Elizabeth Q. Hinckle (CA)
Yuval Miller (CA)
Kyrsten Skogstad (CA)
Elizabeth H. Jackson (CA)

Robert P. Cowell (1931-1980)

of counsel:
Philip Paul Bowe (CA)

McCracken, Stemerman & Holsberry

1630 S. Commerce Street, Suite A-1
Las Vegas, Nevada 89102
702.386.5107
Fax 702.386.9848

December 14, 2012

Via U.P.S. Overnight Delivery

Director
News Division
Office of the Assistant Secretary for Public Affairs
Department of Health & Human Services
7700 Wisconsin Ave. Suite 920
Bethesda, MD 20814

RE: *FOIA Appeal of FDA's Redactions from 483 Report on St Jude Medical Inc.-Sylmar, Case No. 2012-8094*

Dear Director:

On behalf of UNITE HERE, we hereby appeal FDA Staff's denial of our request under FOIA seeking a reduction in Staff's redactions in the 483 Report attached hereto as Exhibit A. In this 483 Report, FDA investigators found various problems with this Company's testing and monitoring process for its Durata-brand Implantable Cardioverter Defibrillator ("ICD") system. Staff's denial (Ex. B hereto) merely followed a form rather than responding to the two well-considered reasons we gave (in Exhibits C and D hereto) for the inapplicability of Exemption 4[i] *[Endnote i]* to most of the data requested:

First, Staff improperly excluded any details of any potential or actual problems for patients which were considered by SJM and the FDA: one has no way of knowing whether the FDA investigator was looking solely into cosmetic problems with ICD devices or instead whether their leads break open and cause metal wires to press against a patient's heart or veins.[ii] *[Endnote ii]* Exemption 4 does not privilege information which is embarrassing to a manufacturer because it shows potential safety problems.

Second, most of the potential and actual problems with ICD devices and patients are well-publicized already. It is settled law that Exemption 4 does not cover facts which are already in the public domain (such as the fact that SJM-Sylmar manufactures an ICD device named Durata, which was not redacted). Here, everything about the components of these ICD devices was redacted, but SJM has already made public a good deal of information about what components it uses and in what configuration, indeed touting these in its advertising (presented in Exhibit D).

We now analyze each of these two issues in more detail.

I. INFORMATION AS TO WHAT PROBLEMS WERE CONSIDERED BY THE INVESTIGATOR AND SJM SHOULD NOT HAVE BEEN REDACTED

Most of the redactions appear designed to prevent customers from learning about likely safety problems, rather than preventing release of trade secrets or similar proprietary information about these devices. This is contrary to the caselaw interpreting Exemption 4:

> "[t]he important point for competitive harm in the FOIA context ... is that it be limited to harm flowing from the affirmative use of proprietary information by competitors. Competitive harm should not be taken to mean simply any injury to competitive position, as might flow from customer or employee disgruntlement or from the embarrassing publicity attendant upon public revelations concerning, for example, illegal or unethical payments to government officials or violations of civil rights, environmental or safety laws."

Public Citizen Health Research Group v. FDA, 704 F. 2d 1280, 1291 n. 30 (D.C. Cir. 1983)

Accord, *CNA Fin'l v. Donovan*, 830 F.3d 1132 (D.C. Cir. 1987); *General Electric v NRC*, 750 F.2d 1394, 1402-3 (7th Cir. 1984)("While General Electric's competitors in the nuclear-reactor business would no doubt be delighted to be able to flag around to their customers a report in which General Electric criticizes its own reactor design, the competitive harm that attends any embarrassing disclosure is not the sort of thing that triggers exemption 4.")

Here, UNITE HERE is not a competitor, nor trying to aid competitors, nor would competitors be able to steal St Jude's ideas as a result of FDA releasing the redacted information. Rather UNITE HERE is a labor union with over 250,000 members which co-sponsors health plans heavily burdened by the current costs of healthcare and thus frankly outraged at being expected by manufacturers to bear costs for dealing with their mistakes such as reimbursing doctors and hospitals for re-checking already-implanted ICD devices. Concern about the safety of SJM's Durata devices is far from speculative, given the recent Class 1 recall of its Riata cardiac devices and recent Wall Street Journal and New York Times articles reporting on (1) SJM long ignored physician complaints about the Riata well before the recall (Ex. E hereto), (2) SJM now uses some similar technology in the Durata, leading some prominent physicians to recommend against Durata's use (Ex. D9), and (3)

SJM using a compound called Optim for insulating its leads (which run from the device up the patient's veins into the heart which other researchers found to degrade too quickly (Ex. D8).

The redactions exclude every reference to the potential or actual problems considered or found with any device. The public is entitled to know which problems are being examined by this ICD manufacturer (and reviewed by FDA), and which problems are being ignored. Were the problems cosmetic or functional? Are the problems analyzed of serious risk to patients or miniscule risk? For example, on page 2 para B there is a reference to a test which is supposed to avoid a problem (apparently a problem for physicians and patients), but the problem has been deleted: "[ ] test, which ensure the [ ] is not greater than [ ] to prevent a potential [ ]." (In addition to knowing what problems are being considered, the public is also entitled to know what tolerances are being used).

It is not as if the risks involved with SJM's ICD devices are a secret: the failures of SJM's prior model (the Riata) in resisting abrasion resulting in conductors extruding and/or electrical abnormalities have become very public. SJM's own advertising claims Durata is superior in avoiding these failures to earlier Riata models and to its competitors' products. Ex.D1 hereto. Further risks are presented on SJM's website. Ex. D2. Access to the data redacted from this 483 will allow physicians, patients and regulators to assess the accuracy of such advertising about problem avoidance, and help policymakers and the public assess the quality of the FDA's approval and review procedures.

It is well settled that Exemption 4 does not permit the redaction of information available in the public domain, even if available in a different format that is harder to comprehend. See, e.g., *CNA Financial v Donovan*, supra, 832 F.2d at 1154 ("To the extent that any data requested under FOIA are in the public domain, the submitter is unable to make any claim to confidentiality — a sine qua non of Exemption 4."); *Davis v. United States Dep't of Justice*, 968 F.2d 1276, 1280 (D.C.Cir.1992) ("[A] showing of public availability renders the FOIA exemptions inapplicable....").

Similarly-inappropriate redactions of information about problems occurred in the following instances:

p. 3 para. 3(A)("a mitigation addressing [ ]")

p. 3 para. 3(A(b)("4 of the total population of 30 canines implanted to support a samples size of 21 had [ ]")

p. 3 para. 3(A)(c)("you failed to evaluate one of the study results which stated [ ]")

p. 3 para. 3 (B) two references to "severity of [ ] and a probability of [ ] when your design team stated the Durata design decreased the risk of this [ ] root cause."

p. 5 para. 7 (A)(d)("the problem of [ ] in your lead continued")

pp. 5-6 para. 7(A)(e)("the mitigation identified in the risk analysis failed and you continued to have the problem of [ ]")

II. MANY COMPONENTS OF THE DURATA ICD SYSTEM ARE NOT CONFIDENTIAL BECAUSE SJM HAS REVEALED THEM ELSEWHERE

We suspect some redactions may be of the name of the Optim insulating material used in Durata and/or other components of Durata revealed by SJM elsewhere. Indeed, SJM boasts about using Optim and describes what its components are. Exs. D1, D3. D5. Some redactions may be of the types and/or configuration of wires and insulation inside the Durata lead, but again these have already been made public (and touted) by SJM. See, e.g., Exs. D1 at pp. 3-4, 6, 8; D3 at pp. 4, 15, 19-21, 24, 29; D6; D7, D10. Further, SJM boasts about various supportive studies (see, e.g., D1 at pp. 12-16; D3 at pp. 10-12, 30-50; D6 at p. 2).) One of these may very well be the study about which information was redacted from the 483 on p. 3 para. 3A.

Please note that if you deny this appeal, under *General Electric*, supra and other cases, we are entitled to an explanation of such denial which responds to the points above. If you have any questions about this appeal we would be willing to present oral argument by phone or in person. Thanks very much for your consideration.

Respectfully,

Andrew Kahn
Attorney for UNITE HERE

AJK/vo

Encls:

ENDNOTES

---

[i] *[Endnote i]* Exemption 4 is for trade secrets or confidential business information, defined under HHS regulation (45 CFR 5.65) as follows:

5.65 Exemption four: Trade secrets and confidential commercial or financial information. We will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

(a) Trade secrets. A trade secret is a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

(b) Commercial or financial information. We will not disclose records whose information is "commercial or financial," is obtained from a person, and is "privileged or confidential."

(1) Information is "commercial or financial" if it relates to businesses, commerce, trade, employment, profits, or finances (including personal finances). We interpret this category broadly.

(2) Information is "obtained from a person" if HHS or another agency has obtained it from someone outside the Federal Government or from someone within the Government who has a commercial or financial interest in the information. "Person" includes an individual, partnership, corporation, association, state or foreign government, or other organization. Information is not "obtained from a person" if it is generated by HHS or another federal agency. However, information is "obtained from a person" if it is provided by someone, including but not limited to an agency employee, who retains a commercial or financial interest in the information.

(3) Information is "privileged" if it would ordinarily be protected from disclosure in civil discovery by a recognized evidentiary privilege, such as the attorney-client privilege or the work product privilege. Information may be privileged for this purpose under a privilege belonging to a person outside the government, unless the providing of the information to the government rendered the information no longer protectable in civil discovery.

(4) Information is "confidential" if it meets one of the following tests:

(i) Disclosure may impair the government's ability to obtain necessary information in the future;

(ii) Disclosure would substantially harm the competitive position of the person who submitted the information;

(iii) Disclosure would impair other government interests, such as program effectiveness and compliance; or

(iv) Disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market by their owner.

The following questions may be relevant in analyzing whether a record meets one or more of the above tests: Is the information of a type customarily held in strict confidence and not disclosed to the public by the person to whom it belongs? What is the general custom or usage with respect to such information in the relevant occupation or business? How many, and what types of, individuals have access to the information? What kind and degree of financial injury can be expected if the information is disclosed?

ENDNOTES

[ii] *[Endnote ii]* The NHLBI website contains this useful summary of how an ICD works and what it is for: "An implantable cardioverter defibrillator (ICD) is a small device that's placed in the chest or abdomen. Doctors use the device to help treat irregular heartbeats called arrhythmias.... An ICD uses electrical pulses or shocks to help control life-threatening arrhythmias, especially those that can cause sudden cardiac arrest (SCA). SCA is a condition in which the heart suddenly stops beating. If the heart stops beating, blood stops flowing to the brain and other vital organs. SCA usually causes death if it's not treated within minutes. * * * An ICD has wires with electrodes on the ends that connect to your heart chambers [commonly called "leads"]. The ICD will monitor your heart rhythm. If the device detects an irregular rhythm in your ventricles, it will use low-energy electrical pulses to restore a normal rhythm. If the low-energy pulses don't restore your normal heart rhythm, the ICD will switch to high-energy pulses for defibrillation. The device also will switch to high-energy pulses if your ventricles start to quiver rather than contract strongly." It should be noted that FDA has recently approved an alternative technology that does not rely on intravenous leads.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)	DEFENDANTS
UNITE HERE	FOOD & DRUG ADMINISTRATION
(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.) Andrew J. Kahn and Sarah Grossman-Swenson Davis, Cowell & Bowe, LLP, 595 Market Street, Suite 1400 San Francisco, CA 94105 (415) 597-7200	Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1 U.S. Government Plaintiff ☑ 3 Federal Question (U.S. Government Not a Party)

☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☐ Yes ☑ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☑ No ☐ MONEY DEMANDED IN COMPLAINT: $ 0

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Violation of FOIA, 5 USC section 552

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES	CONTRACT	TORTS	TORTS	PRISONER	LABOR
☐ 400 State Reapportionment	☐ 110 Insurance	PERSONAL INJURY	PERSONAL PROPERTY	PETITIONS	☐ 710 Fair Labor Standards Act
☐ 410 Antitrust	☐ 120 Marine	☐ 310 Airplane	☐ 370 Other Fraud	☐ 510 Motions to Vacate Sentence Habeas Corpus	☐ 720 Labor/Mgmt. Relations
☐ 430 Banks and Banking	☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 371 Truth in Lending	☐ 530 General	☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 450 Commerce/ICC Rates/etc.	☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 380 Other Personal Property Damage	☐ 535 Death Penalty	☐ 740 Railway Labor Act
☐ 460 Deportation	☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Fed. Employers' Liability	☐ 385 Property Damage Product Liability	☐ 540 Mandamus/ Other	☐ 790 Other Labor Litigation
☐ 470 Racketeer Influenced and Corrupt Organizations	☐ 151 Medicare Act	☐ 340 Marine	BANKRUPTCY	☐ 550 Civil Rights	☐ 791 Empl. Ret. Inc. Security Act
☐ 480 Consumer Credit	☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 422 Appeal 28 USC 158	☐ 555 Prison Condition	PROPERTY RIGHTS
☐ 490 Cable/Sat TV	☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 423 Withdrawal 28 USC 157	FORFEITURE / PENALTY	☐ 820 Copyrights
☐ 810 Selective Service	☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	CIVIL RIGHTS	☐ 610 Agriculture	☐ 830 Patent
☐ 850 Securities/Commodities/ Exchange	☐ 190 Other Contract	☐ 360 Other Personal Injury	☐ 441 Voting	☐ 620 Other Food & Drug	☐ 840 Trademark
☐ 875 Customer Challenge 12 USC 3410	☐ 195 Contract Product Liability	☐ 362 Personal Injury-Med Malpractice	☐ 442 Employment	☐ 625 Drug Related Seizure of Property 21 USC 881	SOCIAL SECURITY
☐ 890 Other Statutory Actions	☐ 196 Franchise	☐ 365 Personal Injury-Product Liability	☐ 443 Housing/Accommodations	☐ 630 Liquor Laws	☐ 861 HIA (1395ff)
☐ 891 Agricultural Act	REAL PROPERTY	☐ 368 Asbestos Personal Injury Product Liability	☐ 444 Welfare	☐ 640 R.R. & Truck	☐ 862 Black Lung (923)
☐ 892 Economic Stabilization Act	☐ 210 Land Condemnation	IMMIGRATION	☐ 445 American with Disabilities - Employment	☐ 650 Airline Regs	☐ 863 DIWC/DIWW (405(g))
☐ 893 Environmental Matters	☐ 220 Foreclosure	☐ 462 Naturalization Application	☐ 446 American with Disabilities - Other	☐ 660 Occupational Safety /Health	☐ 864 SSID Title XVI
☐ 894 Energy Allocation Act	☐ 230 Rent Lease & Ejectment	☐ 463 Habeas Corpus-Alien Detainee	☐ 440 Other Civil Rights	☐ 690 Other	☐ 865 RSI (405(g))
☑ 895 Freedom of Info. Act	☐ 240 Torts to Land	☐ 465 Other Immigration Actions			FEDERAL TAX SUITS
☐ 900 Appeal of Fee Determination Under Equal Access to Justice	☐ 245 Tort Product Liability				☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 950 Constitutionality of State Statutes	☐ 290 All Other Real Property				☐ 871 IRS-Third Party 26 USC 7609

SACV13-0227

FOR OFFICE USE ONLY: Case Number: _____

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☑ No ☐ Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☑ No ☐ Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:
(Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles and Orange Counties	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☑ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange County	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ **Date** February 7, 2013

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Central District of California

UNITE HERE

Plaintiff(s)

v.

FOOD & DRUG ADMINISTRATION

Defendant(s)

SACV13-0227 JVS (MLGx)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Food & Drug Administration
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612

A lawsuit has been filed against you.

Within 60 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Andrew J. Kahn
Sarah Grossman-Swenson
DAVIS, COWELL & BOWE, LLP
595 Market Street, Suite 1400
San Francisco, CA 94105

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

FEB - 8 2013

Date: _____

CLERK OF COURT

JULIE PRADO

_____

Signature of Clerk or Deputy Clerk

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge James V. Selna and the assigned discovery Magistrate Judge is Marc Goldman.

The case number on all documents filed with the Court should read as follows:

SACV13- 227 JVS (MLGx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

---

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[ ] **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

[x] **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

[ ] **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.